UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte STEPHANIE K. CLENDENNEN and
JILL A. KELLOGG

Appeal No. 2005-0905
Application No. 09/811,093

ON BRIEF

Before WILLIAM F. SMITH, GREEN, and ADAMS, Administrative Patent Judges.

WILLIAM F. SMITH, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the examiner's rejection of claims 1, 7, 9-12, 15, and 19-23. Claim 5 is pending and is objected to as being dependent upon a rejected base claim.

Claims 1, 7, and 15 are representative of the subject matter on appeal and read as follows:

1. An isolated nucleic acid molecule comprising a promoter operably linked to a heterologous protein-encoding polynucleotide sequence, wherein the promoter consists of a portion of the nucleotide sequence presented as SEQ ID NO:42 and directs fruit-associated expression of the protein in a plant cell.

7. A plant expression vector comprising the nucleic acid molecule of claim 1.

15. A method of expressing a heterologous protein-encoding polynucleotide sequence in fruit of a transgenic plant, comprising:

(a) transforming plant cells with a plant expression vector according to claim 7;

(b) culturing said plant cells in a culturing medium containing a selection agent to select for transformed plant cells; and

(c) growing said transformed plant cells to produce a transgenic fruit-bearing plant,

wherein the heterologous protein-encoding polynucleotide sequence is expressed in fruit of said transgenic fruit-bearing plant.

Claims 1, 7, 9-12, 15, and 19-23 stand rejected under 35 U.S.C. § 112, first paragraph (written description and enablement). We reverse.

Background

The technology described in the specification is summarized as follows:

> The present invention provides upstream regulatory regions (promoter sequences) from a number of genes in melon that are expressed primarily or exclusively in fruit including cmAC01, cmACO1/TE4, MEL7, MEL2, cm6E, and cm2F.
>
> Melon fruit-associated gene expression mediated by the promoters of the invention may be (1) ethylene regulated, (2) induced by changes in ethylene concentration in the plant, and/or (3) activated, or primarily activated, during later stages of fruit development and/or early stages of fruit ripening.
>
> Exemplary melon fruit-associated promoters include cmACO1/TE4 (SEQ ID NO:41), MEL7 (SEQ ID NO:42), MEL2 (SEQ ID NO:43), 6E (SEQ ID NO:44) and 2F (SEQ ID NO:45).

Specification, page 4, lines 18-26.

Of particular importance in this appeal is the promoter sequence identified as MEL7 in the specification since the claims on appeal are directed to specified portions of the nucleotide sequence presented as SEQ ID NO:42. Further information in regard to the discovery of MEL7 is provided in the specification as follows:

> RAP-screening was used to isolate a particularly abundant transcript fragment from ripe melon fruit. The isolated transcript (melrapF = MEL7, GenBank Accession Z70522) was shown to be relatively fruit-specific and ripening-associated by Northern blot analysis. The transcript fragment was cloned and sequenced, and using gene-specific sequence information, upstream regulatory regions were amplified from melon genomic DNA.

Specification, page 11, lines 28-32. Further information concerning the isolation and characterization of MEL7 is set forth in Example 2 of the application. The activity of MEL7 was evaluated in transient assay system using the GUS reporter gene. See, e.g., Example 4. The data set forth in Example 4 are stated to "suggest that the melon fruit-associated promoters described [in the specification] exhibit significant promoter activity in ripe melon fruit, the intended target tissue."

Discussion

1. Written description.

"The 'written description' requirement serves a teaching function, ... in which the public is given 'meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time.'" University of Rochester v. G.D. Searle & Co., Inc., 358 F.3d 916, 922, 69 USPQ2d 1886, 1891 (Fed. Cir. 2004) (citation omitted).

Another "purpose of the 'written description' requirement is ... [to] convey with reasonable clarity to those skilled in the art that, as of the filing date [ ], [the applicant] was in possession of the invention." Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). See also Enzo Biochem Inc. v. Gen-Probe Inc., 296 F.3d 1316, 1329, 63 USPQ2d 1609, 1617 (Fed. Cir. 2002). The requirement is satisfied when the specification "set[s] forth enough detail to allow a person of ordinary skill in the art to understand what is claimed and to recognize that the inventor invented what is claimed." University of Rochester, 358 F.3d at 928, 69 USPQ2d at 1896. Whether or not a specification satisfies the requirement is a question of fact, which must be resolved on a case-by-case basis (Vas-Cath, 935 F.2d at 1562-63, 19 USPQ2d at 1116), and it is the examiner's "initial burden [to] present[ ] evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims" (In re Wertheim, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976)).

"[A]pplicants have some flexibility in the 'mode selected for compliance' with the written description requirement" (University of Rochester, 358 F.3d at 928, 69 USPQ2d at 1896); it is well settled that actual reduction to practice is not necessary to satisfy the requirement (id., at 926, 69 USPQ2d at 1894). In University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997), the court discussed the application of the written description requirement to inventions in the field of

biotechnology, stating that "[a] written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." Id. at 1567, 43 USPQ2d at 1405. The court also stated that

> a generic statement such as 'vertebrate insulin cDNA' or 'mammalian insulin cDNA,' without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.

Id. at 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material" (id.), but "[a] description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." Id. Whether the level of disclosure in the specification would have allowed one skilled in the art to recognize that the inventor invented what is claimed is a question of fact. The USPTO has summarized a number of factors to be considered in making this determination; they include

"the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention." Guidelines for Examination of Patent applications Under the 35 U.S.C. § 112, ¶ 1, "Written Description" Requirement, 66 Fed. Reg. 1099, 1106 (Jan. 5, 2001). "Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." Id.

The examiner's position in regard to the written description rejection is summarized by the examiner stating "[t]he specification does not describe any portion of SEQ ID NO:42, other than bases 156-1708, that has fruit-associated promoter activity, and hence the specification does not describe a representative number of the claimed genus of promoter fragments." Examiner's Answer, page 6.

Here, the claims on appeal set forth that the isolated nucleic acid molecule must direct fruit-associated expression of the heterologous protein in a plant cell. Furthermore, the claims require that the isolated nucleic acid molecule be a "portion of the nucleotide sequence presented as SEQ ID NO:42." Thus, the claims on appeal couple, at the least, a partial structure with a function. The examiner has failed to provide any analysis why these facts do not provide written descriptive support for the claimed subject matter. As is apparent, the examiner's position is premised upon the fact that appellants have only

explicitly described a certain portion of the nucleotide sequence presented as SEQ ID NO:42 as possessing the claim promoter function. However, the Federal Circuit has "explained that functional descriptions of genetic material can, in some cases, meet the written description requirement if those functional characteristics are 'coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.'" University of Rochester v. G.D. Searle & Co., 358 F.3d 916, 925, 69 USPQ2d 1886, 1893 (Fed. Cir. 2004) (internal citations omitted). Instead of setting forth a studied analysis of the factors set forth in the written description guidelines and relevant Federal Circuit precedent, the examiner has improperly imposed a per se rule that appellants can only claim the nucleotide sequence explicitly described as having the promoter function.

The examiner's written description rejection is reversed.

2. Enablement.

The examiner's position in regard to the enablement rejection is set forth at pages 12-13 of the Examiner's Answer as follows:

> The specification does not provide any guidance as to which fragments of SEQ ID NO: 42, other than nucleotides 156-1708, retain its fruit-associated promoter activity. No information is provided at all concerning the regions of the MEL7 promoter of nucleotides 156-1708 of SEQ ID NO: 42 that are essential to its fruit-associated promoter activity, and which must be present in all portions of SEQ ID NO: 42 that have fruit-associated transcriptional activity. See Genentech, Inc. v. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that 'the specification, not the knowledge of one skilled in the art' must supply the enabling aspects of the invention. One skilled in the art cannot predict what

> portions of bases 156-1708 of SEQ ID NO: 42, or other portions of SEQ ID NO: 42, retain this activity. Further, it is noted that only bases 156-1708 of SEQ ID NO: 42 are MEL7 promoter sequences. In the absence of further guidance, one skilled in the art is left to make all possible fragments of all possible sizes and from all possible regions of SEQ ID NO: 42 and test them for retention of activity, which amounts to undue experimentation. As SEQ ID NO: 42 is 1735 bases long, this is not a trivial matter, as the claims encompass portions of SEQ ID NO: 42 of any and all sizes of a nucleotide or more. Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

Examiner's Answer, paragraph bridging pages 12-13.

Here, the examiner has failed to provide factual support for her conclusion that it would be undue experimentation to make and use the claimed invention. Our appellate reviewing court set forth factors to take into account when determining whether a given claim is enabled under 35 U.S.C. § 112, first paragraph, in In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) as follows:

> Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman, [230 USPQ 546, 547 (BdPatAppInt 1986)]. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. (footnote omitted).

Here the examiner has only focused on the amount of experimentation and has not taken into account such other factors such as relative skill in the art and relevant prior

art. As set forth in PPG Indus., Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1564, 37 USPQ2d 1618, 1623 (Fed. Cir. 1996):

> In unpredictable art areas, this court has refused to find broad generic claims enabled by specifications that demonstrate the enablement of only one or a few embodiments and do not demonstrate with reasonable specificity how to make and use other potential embodiments across the full scope of the claim. See, e.g., In re Goodman, 11 F.3d 1046, 1050-52, 29 USPQ2d 2010, 2013-15 (Fed. Cir. 1993); Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d. 1200, 1212-14, 18 USPQ2d 1016, 1026-28 (Fed. Cir.), cert. denied, 502 U.S. 856 (1991); In re Vaeck, 947 F.2d at 496, 20 USPQ2d at 1445. Enablement is lacking in those cases, the court has explained, because the undescribed embodiments cannot be made, based on the disclosure in the specification, without undue experimentation. But the question of undue experimentation is a matter of degree. The fact that some experimentation is necessary does not preclude enablement; what is required is that the amount of experimentation "must not be unduly extensive." Atlas Powder Co., v. E.I. DuPont De Nemours & Co., 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984). The Patent and Trademark Office Board of Appeals summarized the point well when it stated:
>
> The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed.
>
> Ex parte Jackson, 217 USPQ 804, 807 (1982).

The work needed to identify additional nucleic acid fragments

having the claimed promoter function may be tedious and laborious, but on this record, the examiner has not established that the work would amount to undue experimentation.

The examiner's enablement rejection is reversed.

The decision of the examiner is reversed.

REVERSED

William F. Smith
Administrative Patent Judge

Donald E. Adams
Administrative Patent Judge

Lora M. Green
Administrative Patent Judge

) BOARD OF PATENT
) APPEALS AND
) INTERFERENCES

Exelixis, Inc.
Patent Department
170 Harbor Way
P.O. Box 511
South San Francisco, CA 94083-0511

dem